

<b>Case Number:</b>	CM15-0065019		
<b>Date Assigned:</b>	04/17/2015	<b>Date of Injury:</b>	09/15/2011
<b>Decision Date:</b>	07/17/2015	<b>UR Denial Date:</b>	03/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/03/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: New York  
 Certification(s)/Specialty: Emergency Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 64 year-old female who reported shoulder pain after an injury on 09/15/2011. The mechanism of injury was not described in the records. She was diagnosed with a rotator cuff tear. Treatment to date has included a right shoulder rotator cuff repair and subacromial decompression in 2013, and medications. The drug powders and base cream appealed to Independent Medical Review were billed from an office visit date of 12/18/14. The billing was for the individual drug components and does not reflect any drug combinations in the final product. The PR2 of 12/15/14 mentions the neck and shoulder and that the injured worker was doing well. Current medications were Celebrex and Neurontin, which were continued. Topical compound creams were dispensed: cyclobenzaprine-lidocaine, flurbiprofen-lidocaine, and gabapentin-amitriptyline-capsaicin. There was no discussion of the specific indications for any of these medications. On 3/9/15 Utilization Review non-certified the drug powders and cream referred for this Independent Medical Review appeal. The MTUS was cited.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Retrospective (DOS: 12.18.14) Flurbiprofen powder 30 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Flurbiprofen was dispensed as a combination of flurbiprofen-lidocaine. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in combination with flurbiprofen is not Lidoderm. Per the MTUS, topical NSAIDs for short term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is no good evidence supporting topical NSAIDs for shoulder or axial pain. This injured worker is already taking an oral NSAID, making a topical NSAID duplicative and unnecessary, as well as possibly toxic. The treating physician did not provide any indications or body part intended for this NSAID. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.

**Retrospective (DOS: 12.18.14) Lidocaine 7.5 grams:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Lidocaine was dispensed as a combination of flurbiprofen-lidocaine. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in combination with flurbiprofen is not Lidoderm and is not recommended. Lidocaine was prescribed in combination with flurbiprofen, which is also not indicated (see above). The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.

**Retrospective (DOS: 12.18.14) Versapro base cream 112.5 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Versapro base cream was dispensed in combination with the active ingredients listed in the reviews above and below. As discussed elsewhere, the active ingredients are not supported by the guidelines. There is no medical necessity for the base cream since none of the active ingredients are medically necessary. The above request is not medically necessary.

**Retrospective (DOS: 12.18.14) Gabapentin powder 15 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Gabapentin was dispensed as a combination of gabapentin-amitriptyline-capsaicin. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Per the MTUS citation, there is no good evidence in support of topical gabapentin and it is not recommended. It is therefore not medically necessary.

**Retrospective (DOS: 12.18.14) Amitriptyline HCL powder 7.5 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Amitriptyline was dispensed as a combination of gabapentin-amitriptyline-capsaicin. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As discussed above, gabapentin is not recommended or medically necessary. Amitriptyline was dispensed as combination product with gabapentin, making the entire compound not medically necessary.

**Retrospective (DOS: 12.18.14) Capsaicin powder 0.0375 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Capsaicin was dispensed as a combination of gabapentin-amitriptyline-capsaicin. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As discussed above, gabapentin is not recommended or medically necessary. Capsaicin was dispensed as combination product with gabapentin, making the entire compound not medically necessary. In addition, the injured worker does not appear to have the necessary indications for capsaicin per the MTUS. The MTUS states that capsaicin is only recommended when other treatments have failed. This injured worker has not failed adequate trials of other, more conventional treatments. The treatments to date with NSAIDs and oral gabapentin are reportedly successful. Capsaicin is also not medically necessary based on the lack of indications per the MTUS.

**Retrospective (DOS: 12.18.14) Versapro base cream 127.46 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Versapro base cream was dispensed in combination with the active ingredients listed in the reviews above and below. As discussed elsewhere, the active ingredients are not supported by the guidelines. There is no medical necessity for the base cream since none of the active ingredients are medically necessary. The above request is not medically necessary.

**Retrospective (DOS: 12.18.14) Cyclobenzaprine HCL powder 15 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Cyclobenzaprine was dispensed as a combination of cyclobenzaprine-lidocaine. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Cyclobenzaprine was dispensed in combination with lidocaine, neither of which is recommended per the MTUS. Per the MTUS citation, there is no good evidence in support of topical muscle relaxants; these agents are not recommended. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.

**Retrospective (DOS: 12.18.14) Lidocaine HCL powder 3 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Lidocaine was dispensed as a combination of cyclobenzaprine-lidocaine. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not

recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Cyclobenzaprine was dispensed in combination with lidocaine, neither of which is recommended per the MTUS. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in this case is not Lidoderm. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.

**Retrospective (DOS: 12.18.14) Versapro base cream 132 grams: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** Versapro base cream was dispensed in combination with the active ingredients listed in the reviews above and below. As discussed elsewhere, the active ingredients are not supported by the guidelines. There is no medical necessity for the base cream since none of the active ingredients are medically necessary. The above request is not medically necessary.